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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,063	08/08/2001	Scott C. Barnes	17644-66	2615

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04/09/2003

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EXAMINER

JOYNES, ROBERT M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/09/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,063

Applicant(s)

BARNES ET AL.

Examiner

Robert M. Joynes

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Receipt is acknowledged of applicants' Information Disclosure Statement filed on January 3, 2003 and Amendment filed on January 21, 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9-18, 20-25, 28, 32-40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Cilento et al. (US 5059189). Cilento teaches an adhesive dressing for use on human skin (Col. 4, lines 8-23). The adhesive layer of the dressing comprises a polyisobutylene component (Col. 4, lines 24-34), styrene copolymers (Col. 4, lines 35-51), water-soluble agents such as hydrocolloid gums (Col. 4, line 52 – Col. 5, line 13) as well as mineral oil, tackifiers and antioxidants (Col. 5, lines 14-37). The dressing further comprises a backing film (Col. 5, line 52 – Col. 6, line 7). An active agent is incorporated into the adhesive layer (Col. 6, lines 8-41). The layers can be formed through calendaring (Col. 7, lines 10-38). The adhesive layer is from about 20 to about 100 millimeters (Col. 5, lines 38-42) and the polymeric backing layer is from about 1 to 5 millimeters (Col. 6, lines 3-5).

The teachings of Cilento therefore anticipate Claims 1, 2, 9-18, 20-23.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 9-18, 20-25, 28, 32-40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento et al. (US 5059189). The teachings of Cilento are discussed above. Cilento does not teach the exact concentration ranges and layer thickness of the instant claims.

While the reference does not teach the complete concentration or layer thickness ranges, differences in concentration or thickness will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or thickness is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

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At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to adjust the concentrations of the ingredient and to adjust the thickness of the individual layers.

One of ordinary skill in the art would have been motivated to do this to prepare various transdermal compositions with different active agents. The amount and type of active agent would dictate the additional ingredients necessary and the amounts of each ingredient. Thickness is also determined by one of ordinary skill in the art depending on the active agent used and the material used to form the layers.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 3-5, 18, 19, 26 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento et al. in combination with Sablotsky et al. (US 4994278). The teachings Cilento are discussed above. Cilento does not expressly teach that the backing layer comprises ethylene acrylic acrylate or ethylene butyl acrylate or ethylene ethyl acrylate or ethylene methyl acrylate.

Sablotsky teaches that a backing layer for transdermal compositions can be ethylene methyl acrylate (Col. 7, lines 10-18).

Neither Cilento nor Sablotsky teach the exact concentration ranges of the polymeric backing layer.

While the reference does not teach the complete concentration ranges, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is

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critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use any known polymeric component(s) for the backing layer of a transdermal composition.

One of ordinary skill in the art would have been motivated to do this to increase or decrease the barrier properties of the backing layer.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 6-8, 18, 19, 29-31 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento et al. in combination with Sablotsky et al. in further combination with Godbey et al. (US 5372819). The teachings of Cilento and Sablotsky are discussed above. Neither Cilento nor Sablotsky teach that the polymeric backing layer further comprises additional additives.

Godbey teaches a transdermal delivery system in which the backing layer can contain polymer additives such as processing aids, pigments, and lubricants (Col. 4, lines 30-36).

While the reference does not teach the complete concentration ranges, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not

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inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include additives in the polymeric backing layer of a transdermal composition.

One of ordinary skill in the art would have been motivated to do this to change the color of the composition or to change the flexibility of the backing layer.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants' arguments filed on January 21, 2003 have been considered but are not found to be persuasive. Applicants argue that the prior art fails to teach or suggest a hydrocolloid dressing that is manufactured by calendering the adhesive layer and backing layer simultaneously to form the dressing.

The Examiner would like to point out that Claims 1-20 are drawn to a product, a calendered hydrocolloid dressing, which has process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale

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tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). The prior art teaches a dressing that has an adhesive layer with a hydrocolloid component and a backing layer. It is the position of the Examiner that the claimed products appear to be the same.

As for the method claims, it appears that there are 5 manufacturing steps as recited by the claims and not one single manufacturing step. Therefore, applicants' arguments as to a simultaneous manufacturing process are unpersuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

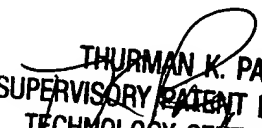
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
April 6, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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